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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,691	01/22/2002	Xuanchuan (Sean) Yu	LEX-0303-USA	5177
24231	7590	10/06/2004	EXAMINER	
LEXICON GENETICS INCORPORATED 8800 TECHNOLOGY FOREST PLACE THE WOODLANDS, TX 77381-1160			NASHED, NASHAAT T	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,691

Applicant(s)

YU ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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The application has been amended as requested in the communication filed July 6, 2004. Accordingly, claim 2 has been cancelled, and new claims 5-8 have been entered.

Claims 1, 3-8 are pending and under consideration.

The abstract of the disclosure is objected to because it does not describe the claimed invention. Correction is required. See MPEP, 608.01(b).

Applicants objected to the objection to the abstract, cite several issued patents having identical abstract, and argue that the Office accepted the abstracts in the issued patents.

Applicants' arguments filed July 6, 2004 have been fully considered, but they are found unpersuasive. The examiner presumes that the cited patents are valid, and thus, can't comment on them. Applicants should note none of these patent is currently being examined. Since applicants have not amended the abstract to describe the claimed invention and conceded that the abstract does not describe the claimed invention, the objection to the abstract remains proper.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, and 3-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth in the prior Office action mailed January 21, 2004.

Claims 1 and 3-8 are also rejected under 35 U.S.C. 112, first paragraph for the reasons set forth in the prior Office action mailed January 21, 2004.

In response to the above rejection applicants argue that they have described many utility for the claimed invention and the Court in *In re Brana* has admonished the

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PTO for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption".

Applicants' arguments filed 7/6/04 have been fully considered, but they are found unpersuasive. The examiner agrees with the applicants that they have taught many possible utilities for the nucleic acid of SEQ ID NO: 1 and the polypeptide of SEQ ID NO: 2 none of which are specific or substantial. Also, the examiner has not confused the utility requirement and the requirements for government approval of drugs. The specification does not identify a single disease, which is related to excess or diminished activity of the phospholipase of SEQ ID NO: 2. Applicants provide a list of references which show that various phospholipase B (Exhibits B-D) have various important biological function, but none of these reference provides a specific or substantial utility for the claimed nucleic acid sequence of SEQ ID NO: 1 or encoding the polypeptide of SEQ ID NO: 2. Exhibits B-D confirm the examiner's opinion regarding the diverse biological functions of phospholipases. While the phospholipase of accession number XP-371487 of Exhibit A may be 99% homologues to that of SEQ ID NO: 2, it is of little relevance to the claimed invention. First it is a statutory requirement that an invention must have a specific or substantial utility as of the application filing date. Second, the accession number is not a prior art and therefore does not provide enablement for the claimed invention. Finally, the accession number does not provide substantial or specific utility for the claimed invention. It should be noted that the examiner has accepted the asserted utility by the applicants for the polypeptide of SEQ ID NO: 2 as phospholipase. The key question here is "does SEQ ID NO: 2 have specific or substantial utility? Neither the specification nor the arguments provided by the applicants point out to a single specific or substantial utility. While sequence homology may provide a plausible function for a polypeptide, sequence homology does not impart neither biological nor chemical functional homology. It is said that the sequences of the present invention encode novel isoforms of human phospholipase B. The examiner can't envision something novel and having well-established utility known to those skilled in the art at the same time of invention. As for the many utilities stated on pages 9-17 of the response which reiterate the many utilities in the specification, said utilities are general uses for a general class of compounds, i. e., DNA, and therefore, do not constitute specific or substantial utility. Thus, the claims remain rejected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

New claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "drawn from the group consisting of" in

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claim 5 renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The only member of the Markush group is SEQ ID NO: 2. One member does not define a group. Claims 6-8 is included in this rejection because they are dependent on claim 5 and do not cure its deficiencies. For examination purposes only, the phrase is deleted from the claim.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner